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| 10/726,605      | 12/04/2003  | John F. Shanley      | 032304-089          | 6950             |

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MENLO PARK, CA 94025

EXAMINER

HOUSTON, ELIZABETH

ART UNIT PAPER NUMBER

3731

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/726,605

Applicant(s)

SHANLEY, JOHN F.

Examiner

Elizabeth Houston

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-37 is/are allowed.
- 6) ☒ Claim(s) 38-40, 42-51 and 53-62 is/are rejected.
- 7) ☒ Claim(s) 41 and 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Objections*

1. Claim 31 is objected to because of the following informalities: Claim 31 recites the limitation "elongated struts have a thickness of at least 0.002 inch". The specification at paragraph [0067] states, "Known expandable tissue supporting devices have a typical wall thickness b of 0.0025 inches (0.0635 mm)" and paragraph [0070] states, "Wall thickness of the present invention may be increased to 0.005 inches (0.127 mm) or greater." No support can be found for a thickness of at least 0.002 inch.
2. Claim 42 is objected to because of the following informalities: In the second line, the word "struts" which was previously deleted from the claim should be removed. In the third line the word "bean" should be replaced with the word "beam". In the fourth line, the word "a strut" which was previously deleted from the claim should be removed.
3. Claim 43 is objected to because of the following informalities: In the second line, the words "axial struts" which were previously deleted from the claim should be removed.
4. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 38-40, 46-48, 50, 51, 54 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein et al. (USPN 5,922,020).

7. Klein discloses a stent (Figs. 17 and 18) comprising a plurality of elongated beams joined together to form a cylindrical device, which is expandable, and a plurality of hinges connecting the beams. The hinge width is smaller than the beam width so that the hinges experience plastic deformation upon expansion while the beams are not plastically deformed. The hinge has a first side surface placed in compression during expansion of the device and a second side surface placed in tension during expansion of the device. The first side has a length smaller than the length of the second side surface.

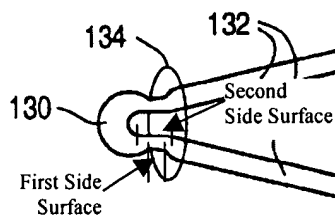


FIG. 18B

8. Since the hinges are asymmetrically configured, they are inherently capable of reaching a predetermined strain upon a first percentage of expansion from an initial diameter and of reaching the predetermined strain level upon a second percentage of compression from the initial diameter, the first percentage being larger than the second.

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Support is found for this in the remarks submitted by the applicant 04/24/06 in the bottom paragraph of page 13. The hinge width is less than  $\frac{2}{3}$  the beam width. A transition between the cross sectional area of the struts elongated beams and the hinges is an abrupt transition and extends less than 10 percent of the length of the strut of the elongated beam. The ratio of the length of the hinge to the length of the elongated beams is 1:6 or less. The first side of the hinge is concave.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 49, 56-60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (USPN 5,922,020) in view of Ndondo-Lay (USPN 6,273,908).

11. Klein discloses all the limitations substantially as claimed as stated above except Klein does not disclose the plurality of holes for containing a beneficial agent.

12. Ndondo-Lay discloses a stent that has a plurality of holes for delivering a beneficial agent. The holes are located on non-deforming elements or second portions with lower strain concentration. The beneficial agent is chemotherapy (Col 8, line 15-18) and the holes are laser-drilled (Col 9, line 59). Ndondo-Lay explains that devices for delivering drugs to a body portion during or after a medical procedure is ideal to prevent

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conditions such as thrombosis, restenosis, and tissue in-growth problems (Col 4, lines 7-21).

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of drug delivering holes onto a stent. Ndondo-Lay provides the motivation for using drug delivery holes in that they are beneficial for further treating diseased vessels and preventing restenosis. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

1. Claim 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Kusleika (USPN 5,722,979).

2. Klein discloses the claimed invention as stated above except Klein does not disclose the device is expandable by a balloon catheter pressurized by an inflation pressure of 1 to 5 atmospheres.

3. Kusleika discloses a balloon catheter that is used to deliver stents where the balloon inflation pressure ranges from 2 to 6 atmospheres (Col 2, line 56-57 and Col 3 lines 28, 46, 62).

4. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a low pressure delivery balloon to deliver a stent in order to minimize potential medical complications such as balloon rupture, or damaging healthy tissue if the balloon is improperly placed (Col 1, lines 24-40). Kusleika offers the

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motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

14. Claims 42-44 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein.

15. Klein discloses the invention substantially as claimed except for the hinge width is no greater than 60% of the hinge thickness and the hinge width is at least 50% smaller than the beam width. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the stent. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

16. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Kusleika and further in view of admission.

17. Klein in view of Kusleika discloses the invention substantially as claimed except for the struts having a thickness of at least 0.002 inches.

18. Admission discloses that in paragraph [0067] of the printed publication "Known expandable tissue supporting devices have a typical wall thickness  $b$  of 0.0025 inches (0.0635 mm)". Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have a thickness of at least 0.002 inches since it was well known in the art.

***Allowable Subject Matter***

19. Claims 27-37 are allowed.
20. Claims 41 and 52 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
21. The following is a statement of reasons for the indication of allowable subject matter: There is no prior art alone or in combination that discloses a stent having a plurality of hinges having a width that is smaller than the beams, and the hinges being in the shape of a *curved beam* along the hinge length having a first arcuate surface and a *second arcuate surface*.

***Response to Arguments***

22. Applicant's arguments with respect to claims 38-62 have been considered but are moot in view of the new ground(s) of rejection.
23. After careful consideration of the double patenting rejection over the '967 patent in view of Klein (USPN 5,922,020), and the rejection over '007 application in view of Klein, examiner has determined that there is no motivation disclosed in Klein to provide the elements that are missing from the '967 patent and the '007 application. Therefore the double patenting rejection has been withdrawn.



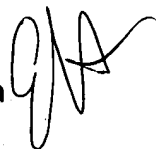
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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh 

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

12/8/06